REMARKS/ARGUMENTS

Specification

Title

The Title has been amended to show the Title as filed in the PCT application and US National Phase application. The Transmittal letter accompanying the National Phase application incorrectly listed the title.

Disclosure

A typographical error, which incorrectly identified Figure 18 as Figure 12, was corrected in various locations in the text. The text accompanying the Figure describes a TLC (thin layer chromatograph). Figure 12 does not show a TLC and Figure 18 is the only TLC.

Claims

35 USC § 102(b) Rejection of Claims 1 - 7

The Office Action rejected Claims 1 - 7 under 35 USC § 102(b) as being anticipated by Yoshikawa *et al* (1991). The Office Action states "Yoshikawa *et al.* teach the water extract from the aerial parts and fruits of *Luffa cylindrical* (Cucurbitaceae) (page 1185, left column, 1st paragraph) with hexane to remove the fatty oil (page 1187, left column, 2nd paragraph from the bottom). Fractions were repeatedly chromatographed on silica gel with $CHCl_3$-MeOH-H_20 (65: 35: 10).

The applicant disagrees with the conclusion in the Office Action that Yoshikawa *et al* (1991) anticipates Claims 1 – 7 in the present application. Independent Claim 1 is a Product by Process claim, and as such, it is the Product that is being claimed. MPEP 2113 states "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself."

The process described in Yoshikawa *et al.* has major and significant differences from the process in Claim 1 and the end-product obtained at the end of the Yoshikawa *et al.* process does not have the characteristics of the product obtained by the process in Claim 1.

The processes under discussion are used to isolate a specific chemical or chemicals from a biological source (plants). The isolation is accomplished by using the chemical's affinity for

various solvents, and partitioning and isolating the desired chemical by a series of steps that causes the chemical to have a greater affinity for one of two solvents or between a substrate and a solvent. Therefore, the order of the steps and solvent used at each step is very important to obtaining a desired chemical. For example; if step A is a non-polar solvent (e.g., hexane) and step B is a polar solvent (e.g., water), then a process that subjects a substrate to Step A then Step B will produce a different product than a substrate to Step B then step A. The first process (A → B) will obtain non-polar chemicals that have a greater affinity to a polar solvent, whereas the second process (B → A) will obtain polar chemicals that have a greater affinity to a non-polar solvent.

For ease of comparison, flow charts have been generated to show the process steps for each reference. Claim 1 (Appendix 1) has several significant differences from Yoshikawa (Appendix 2). Claim 1 is an extraction process of dried powdered plant material with first a polar solvent, then a series a solvent partition steps between the aqueous suspension and hexane, then chloroform, then propanol, and then butanol. The chemicals soluble in Chloroform after being partitioned with Hexane are fractionated by column chromatography into 11 sub-fractions. The final product is obtained in the 9th fraction and characterized by TLC and HPLC.

Yoshikawa's extraction process has a first step with a non-polar solvent (hexane) followed by extraction with water. Even assuming that the milieu of chemicals in the aqueous suspension, at this point, is the same in both processes, Yoshikawa then uses column chromatography with Methanol to obtain 4 sub-fractions. Fractions III and IV are further processed with silica gel chromatography with chloroform:MeoH:H_2O.

The significant differences between the processes in Claim 1 and Yoshikawa *et al.* would suggest to a person of ordinary skill in the art that these processes would obtain different end-products.

Additionally, the end-product obtained by the process in Claim 1 has potent anti-obesity and anti-adipogenic activity, whereas the end-product obtained by the Yoshikawa process has fibrinolysis activity (page 1187, left column, 4th full paragraph). There is no indication that these two end-products are the same chemical.

The differences between the process steps and the activity of the end-products shows that Yoshikawa does not anticipate Claim 1. Claims 2 – 7 and New claim 14 are dependent from Claim 1 and further limit Claim 1, so these claims are also not anticipated by Yoshikawa.

The Examiner is requested to remove Yoshikawa as a 102(b) Prior Art reference since it does generate the product in Claim 1. Claims 2 – 7, and 14, which are dependent from Claim 1, also does generate the product in Yoshikawa. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 1 – 7, and 14.

35 USC § 103(a) Rejection of Claims 1 - 13

The Office Action rejected Claims 1 – 13 under 35 USC § 103(a) as being unpatentable over Yoshikawa *et al* (Chem Pharm Bull 39(5): 1185-1188,1991) in view of Evertz (US 2,242,062), and further in view of Maurya *et al*. (US 6,617,313).

The Office Action stated "Yoshikawa *et al* do not teach hot-water soluble extract, chloroform, composition percentage, and food/beverage. Evertz teaches water-soluble therapeutic principle may be extracted from watermelon seeds, rind, pulp, vine, or roots (page 1, left column, lines 25-30). The dried powder is mixed with water, heated to boiling (page 1, left column, lines 55-60). The product may be given in milk or other liquids (food/beverage) (page 1, right column, lines 27-32). Maurya *et al* teach extracting plant material with hot water. The resultant concentrate was partitioned between hexane, chloroform, propanol and butanol in that order, and then subjected to silica gel chromatography using hexane, chloroform, ethyl acetate and methanol as solvent system (col 6, Example 2). Maurya *et al* also teach that the organic solvent used to remove the non-polar components is selected from the group consisting of hexane, pet ether and chloroform, and the polar solvent used to extract the aqueous layer is selected from ethyl acetate, propanol and butanol (col 5, lines 1-7)."

The applicant disagrees with the conclusion in the Office Action that Claims 1 - 13 are unpatentable over Yoshikawa *et al* (1991) in view of Evertz (US 2,242,062), and further in view of Maurya *et al*. (US 6,617,313). It is important to reiterate that Independent Claim 1 is a Product by Process claim, and as such, it is the Product that is being claimed.

For ease of comparison, flow charts have been generated to show the process steps for each reference. Claim 1 (Appendix 1) has several significant differences from Yoshikawa (Appendix 2), Evertz '062 (Appendix 3) and Maurya '313 (Appendix 4).

The processes described in Yoshikawa *et al.* (1991), Evertz '062 and Maurya '313, and any combination of these processes, have major and significant differences from the process in

Claim 1 and the end-product obtained at the end of the Yoshikawa *et al.*, Evertz '062 or Maurya '313 process does not have the characteristics of the product obtained by the process in Claim 1.

Since this is a Product by Process, it is not sufficient to just show that various chemical procedures are described in a combination of references, it is necessary to show that the chemical procedure that is being added to the primary reference is used on the same starting material that would be present at that stage in the process of the primary reference. If the starting material is different, then the end-product will be different from the product being claimed.

Evertz '062 describes a process that is significantly different from Claim 1, and the combination of the process in Yoshikawa with Evertz '062 does not solve the deficiencies. Even if we assume that the solution after the water extraction step is the same in both Yoshikawa and Evertz '062 processes, and that the end-product of Evertz '062 enters the Yoshikawa process at the step of "Column Chromatography w/ MeOH", the end-product would still be different from Claim 1 because Yoshikawa then uses column chromatography with Methanol to obtain 4 sub-fractions with Fractions III and IV selected for further processing with silica gel chromatography with chloroform:MeoH:H_2O. However, Claim 1 uses a series a solvent partition steps between the aqueous suspension and hexane, then chloroform, then propanol, and then butanol. The chemicals soluble in Chloroform after being partitioned with Hexane are fractionated by column chromatography into 11 sub-fractions. The final product is obtained in the 9th fraction and characterized by TLC and HPLC.

Maurya '313 describes a process that is significantly different from Claim 1, and the combination of the process in Yoshikawa with Evertz '062 and Maurya '313 does not solve the deficiencies. Maurya '313 describes a process for the extraction of the heartwood of *Pterocarpus marsupium* (Indian Kino). The Indian Kino is a medium to large, deciduous tree and can grow up to 30 meters tall. This plant is not closely related to the Cucurbitaceae Family and there is no suggestion in the reference that the end-products would be expected to be the same chemical.

The most significant difference between Claim 1 and Maurya '313, or any combination with Yoshikawa and Evertz '062, is the claimed chemical's solubility in Chloroform, Propanol and Butanol. The claimed chemical is more soluble in Chloroform than the aqueous solution at that step, and the claimed chemical is purified and isolated from the Chloroform partition.

Even if the starting material of the Maurya '313 process was the same as the aqueous solution before the hexane partition in Claim 1, the end-product in Maurya '313 is insoluble in Chloroform and Propanol, and it is finally soluble in the Butanol partition. The end-product of Maurya '313 is purified from the Butanol partition.

The significant differences between the process in Claim 1 and the combination of the Yoshikawa *et al.*, Evertz '062 and Maurya '313 processes would suggest to a person of ordinary skill in the art that these processes would obtain different end-products.

Additionally, the end-product obtained by the process in Claim 1 has potent anti-obesity and anti-adipogenic activity, whereas the end-product obtained by the Evertz '062 process has high blood pressure and bladder activity (column 1, first paragraph), and the end-product obtained by the Maurya '313 process has anti-diabetic activity (column 3, 4th full paragraph).

The differences between the process steps and the activity of the end-products shows that the combination of Yoshikawa, Evertz '062 and Maurya '313 does not generate the same chemical as in Claim 1. Claims 2 – 13 and New claim 14 are dependent from Claim 1 and further limit Claim 1, so these claims are also patentable over the combination of Yoshikawa, Evertz '062 and Maurya '313.

The Examiner is requested to remove Yoshikawa, Evertz '062 and Maurya '313 as 103(a) Prior Art references since they do not generate, alone or in combination, the product in Claims 1 – 14. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 1 - 13.

Conclusion

Claims 1 – 14 are Pending. Claims 1, 2, and 12 are Currently amended. Claims 3 – 11, and 13 have been Previously presented. Claim 14 is New.

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested and it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

A one month extension is requested and payment of the fee for the extension has been paid with the filing of the Response. No additional fees are believed due; however, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to credit card information.

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